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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RIGGS II, LARRY D

ART UNIT

PAPER NUMBER

1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,763	Applicant(s) VOCKLEY ET AL.	
	Examiner LARRY D. RIGGS II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and request for reconsideration filed 29 November 2007 are acknowledged and entered.

Status of Claims

Cancellation of claims 5-11 are acknowledged. Claims 12 and 13 are currently pending and under consideration.

Withdrawn Rejections/Objections

The rejection of claims 7 and 12 under 35 U.S.C. 112, 2nd Paragraph, in the office action mailed 29 May 2007 is withdrawn in view of the amendments and explanation filed 29 November 2007.

The rejection of claims 5-11 under 35 U.S.C. 101, in the Office action mailed 29 May 2007 is withdrawn in view of the amendments filed 29 November 2007.

The rejection of claims 5 and 8-11 under 35 U.S.C. 102(a) over Xu et al., in the Office action mailed 29 May 2007 is withdrawn in view of the amendments filed 29 November 2007.

The rejection of claims 12 and 13 under 35 U.S.C. 102(a) over Lai et al., in the Office action mailed 29 May 2007 is withdrawn in view of the amendments filed 29 November 2007.

The rejection of claim 6 under 35 U.S.C. 103(a) over Xu et al. in the Office action mailed 29 May 2007 is withdrawn in view of the amendments filed 29 November 2007.

The rejection of claim 7 under 35 U.S.C. 103(a) over Xu et al. in view of Benson et al., in the Office action mailed 29 May 2007 is withdrawn in view of the amendments filed 29 November 2007.

Specification

The use of the trademark UNIGENE in the specification, page 9, paragraph 42, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The objection below has been reiterated from the Office Action mailed 29 May 2007.

The information relating to the government contract number on page 1 of the specification is blank. Applicant's arguments have been fully considered but they are not persuasive. With respect to the government contract number, applicant argues "that a reference will be added to the application promptly upon identification." Until such time as a reference is added, the objection shall be maintained.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12 and 13 are amended to recite "output to a memory an identity of those sequences having homology above a threshold with at least one set of organisms other than the set under investigation". Applicants contend that support for the above amendment can be found in the disclosure, e.g. paragraph 9. The specification does not disclose storage in a memory, an identity of those sequences having homology above a threshold with at least one set of organisms other than the set under investigation. The newly added limitation is thus considered as new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 in line 10 and claim 13 in line 15, recite the limitation "the results".

There is insufficient antecedent basis for the limitation.

Claim 13 recites the limitation "the computer program product" in lines 2-3.

There is insufficient antecedent basis for the limitation.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a method and computer program product comprising: obtaining genomic data characteristic of a set of organism under investigation, formatting the genomic data into at least one query-length sequence, each query-length sequence being of a format compatible with a similarity search engine; searching a selected genomic database using the query-length sequence and the similarity search engine, the selected genomic database containing genomic data from a plurality of organisms, parsing the results of the search for those sequences having homology above a threshold with at least one set of organism other than the set under investigation, outputting to a memory an identity of those sequences having homology above a threshold with at least one set of organism other than the set under investigation.

Since the claimed invention involves mathematical algorithm, which is a judicial exception, the following analysis of facts of this particular patent application follows the

rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at

<http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation by the claimed invention because method is only manipulating and categorizing data, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be

limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claim 12 does not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of the questionnaire and scoring of answers, to produce a real-world result. The instant claims are drawn to a method of identifying sequences having homology with sequences of another organism. The last step of the claims includes outputting to a memory an identity of those sequences having homology above a threshold with at least one set of organisms other than the set under investigation, the result of the invention is a set of data, such as sequence data, which, in itself, is not tangible. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

Regarding the computer product claim 13, because the method claims are drawn to nonstatutory subject matter for not producing a useful, concrete and tangible result, the systems that perform the process also do not produce a useful concrete and tangible result, thus also drawn to nonstatutory subject matter.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicant's arguments filed 29 November 2007 have been fully considered but they are not persuasive.

Applicants argue that claims 12 and 13 provide a tangible result by amending said claims to recite "outputting to computer memory the identity of sequences", wherein support for the amendment could be found in the disclosure, specifically, paragraph [0009].

This argument is not found persuasive.

Outputting data, such as "the identity of sequences", to a computer memory is not a tangible result. It is unclear if a user may have access to "the identity of sequences", because at least one embodiment of the claim could provide computer memory that is only accessible to computers and not necessarily to a user. The claims must recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. Likewise applicants are cautioned against introduction of new matter in an amendment. Neither paragraph [0009] or anywhere else in the specification was there support for outputting to computer memory the identity of sequences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (Biochimica et Biophysica acta, 2001, 1517, 449-454) in view of Benson et al., (Nucleic Acids Research, 1993, 21(13), 2963-2965) and further in view of Aoki et al. (US 7,142,989).

Claim 12 is drawn to a method comprising: obtaining genomic data from a first set of organisms, formatting the genomic data into query-length sequences, searching a genomic database using the query-length sequences, wherein the database contains genomic data from a plurality of organisms, parsing the results of the search for

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sequences having homology above a threshold where the sequences come from an organism other than the organism from which the query sequence was derived and outputting to a memory an identity of those sequences.

Lai et al. disclose a method for obtaining EST sequences from humans (page 449, 2nd column, lines 2-4). They format these sequences to be used by a BLAST search engine (page 449, 2nd column, lines 5-6), They search a database of human sequences from the human gene index, HGI (page 449, 2nd column, first paragraph) and they search the GeneBank database, (page 451, left column, second paragraph), and parse the results (page 449, 2nd column, lines 12-13) to identify Drosophila sequences having homology above a given threshold (page 449, 2nd column, lines 7-8).

Lai et al. does not show that the genomic database contains genomic data from a plurality of organisms and outputting the identified sequence to a memory.

Benson et al. shows the GenBank database that contains, as of April 1993, 129 million bases, distributed in 14 different divisions, such as bacterial, viral, mammalian, primate, etc., (see page 2964, right column, last paragraph – page 2965, left column, first paragraph).

Lai et al. and Benson et al. do not show outputting the identified sequence to a memory.

Aoki et al. shows storing identified sequence to a memory after a homology comparison of sequences, (see claims 1, step (b) and 10 step (b)).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of identifying analogous genes by comparative gene identification by Lai et al by providing the information regarding the plurality of organisms within GenBank by Benson et al. and the system of storing the identified sequences in a memory by Aoki et al. because the computer program by Lai et al. would be performed on a computer, wherein results of said program would be stored on said computer system that would contain a memory, e.g. RAM or ROM, (see page 449, right column).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (Biochimica et Biophysica acta, 2001, 1517, 449-454) in view of Benson et al., (Nucleic Acids Research, 1993, 21(13), 2963-2965) and further in view of Aoki et al. (US 7,142,989), as applied to claim 12 above.

Claim 13 is drawn to a computer program product comprising: a computer-readable medium; a genomic data interface module, stored on the medium and operable to couple to a source of genomic data to receive genomic data characteristic of a set of organisms under investigation; a formatting module, stored on the medium and operable to format received genomic data into at least one query-length sequence, each query-length sequence being of a format compatible with a similarity search engine; a search interface module, stored on the medium and operable to interface with the similarity search engine to submit the query-length sequence to a selected genomic database containing genomic data from a substantial plurality of organisms; and a

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search results parsing module, stored on the medium and operable to parse the results of the search of those sequences having homology above a threshold with at least one set of organism other than the set under investigation, and to output to a memory an identity of those sequences having homology above a threshold with at least on set of organisms other than the set under investigation.

In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure*, U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the claimed invention merely makes the method of Lai et al., Benson et al. and Aoki et al. as computer-implemented or automatic and indeed accomplishes the same result. Lai et al. shows a computer program product for carrying out their method, (page 449, right column, lines 9-13). It is thus not sufficient to distinguish over Lai et al., Benson et al. and Aoki et al. Therefore, the claimed invention, i.e. the computer readable medium comprising instructions to execute a process would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Lai et al., Benson et al. and Aoki et al.

One of ordinary skill in the art would have been motivated to make it completely automatic by comprising instructions in the computer readable medium for executing all

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steps of the method to take the obvious advantage of a fully automatic process, i.e. saving time and cost.

There would have been a reasonable expectation of success because the court held regarding software that “writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed.” *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805.

Conclusion

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631

/Shubo (Joe) Zhou/
Shubo (Joe) Zhou, Ph.D.
Primary Examiner